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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,362	11/07/2005	Parag Karmarkar	3514.218	4888

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EXAMINER	
MENDEZ, MANUEL A	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
06/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,362	KARMARKAR ET AL.	
	Examiner	Art Unit	
	Manuel A. Mendez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

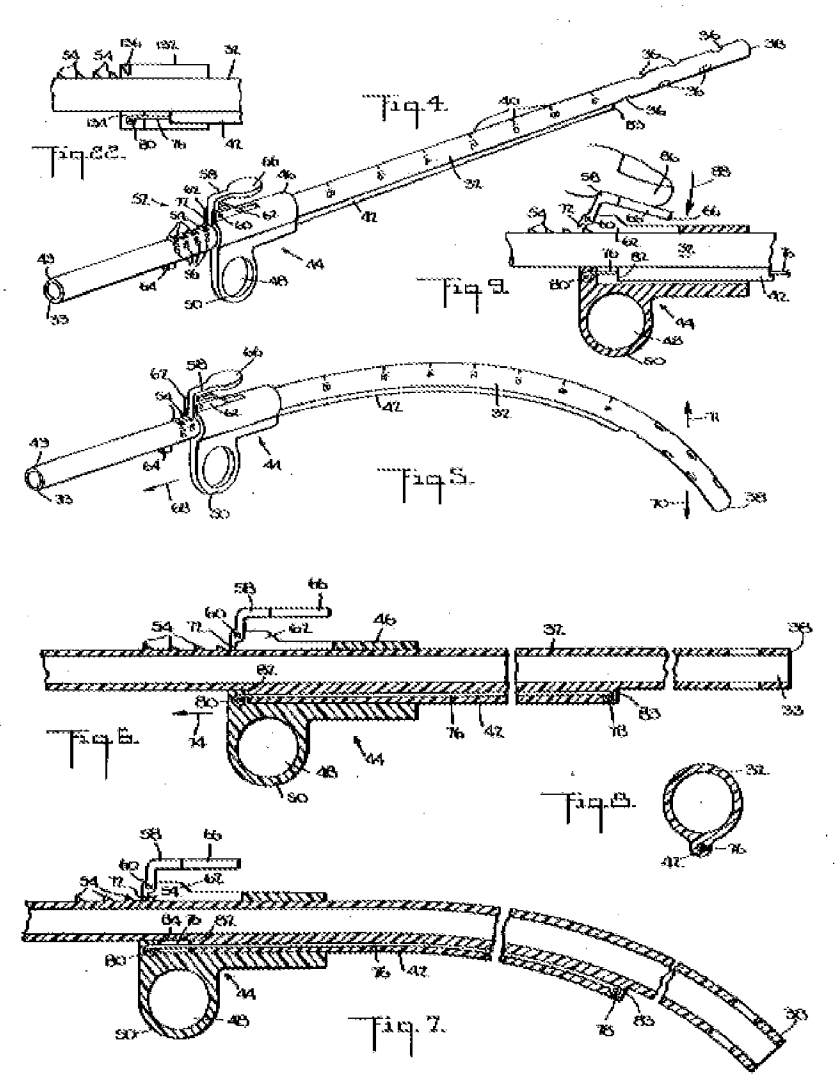
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by **Rosenblum** (US 4976688).



In figures 4, 5, 7, 8, and 9, the cited patent shows a catheter comprising:

- an elongate body;
- a distal section coupled to the body, the distal section being operatively connected to a pull wire, wherein the distal section is deflectable upon application of an external force by a user via the pull wire;
- a longitudinally extending inner lumen defined by the body and the tip, the lumen being adapted to deliver a diagnostic, prophylactic, or therapeutic agent into a subject; and
- a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenblum** (US 4976688) in view of **Middleman** et al. (US 5231989; hereafter Middleman), **Winnie** (US 3856009), or **Sylvanowicz** (US 4935017).

The Rosenblum patent does not disclose an elongate stiffener tube that is slidable longitudinally relative to the body and providing a fulcrum spaced a distance from the distal end of the distal section. Claims 3-5 disclose stiffeners that are located within the body and another design that is a sleeve located over the outer surface of the catheter body. However, both designs would have been considered conventional in the art as evidenced by the teachings of **Middleman, Winnie**, or **Sylvanowicz.**

Middleman shows in figures 1B and 1C, a stiffener that is located within the body of the catheter. The Winnie patent shows in figures 2 and 3, a stiffener that comprises of a sleeve located outside the body of the catheter. The Sylvanowicz patent shows in figures 1-4, another stiffener that comprises of a sleeve located outside the body of the catheter.

Based on the observations above, for a person of ordinary skill in the art, modifying the Rosenblum patent with a stiffeners that are located within the body of the catheter or comprise of a sleeve located over the outer surface of the catheter, would

have been considered obvious in view of the proven conventionality of these enhancements, and moreover, because the addition of a stiffener would have enhanced the maneuverability of the catheter system by providing a more efficient curve adjustment mechanism.

Claims 6-14 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenblum** (US 4976688) in view of **DeLaRama** et al. (US 5381782; hereafter DeLaRama), and in further view of **Middleman** et al. (US 5231989; hereafter Middleman), **Winnie** (US 3856009), or **Sylvanowicz** (US 4935017).

The Rosenbaum patent does not disclose a distal section having a plurality of slots that provide collapsible spaces wherein the pull wire is attached to the distal end of the slotted tube. However, this particular tube enhancement would have been considered conventional in the art as evidenced by the teachings of DeLaRama.

The DeLaRama patent shows in figures 3, 4, and 7, a catheter having a slotted tube having collapsible spaces wherein the pull wire is attached to the distal end of the slotted tube (claims 6-9 and 15). Based on the teachings of DeLaRama, for a person of ordinary skill in the art, modifying the catheter disclosed by Rosenblum with a body having a slotted design with collapsible spaces and a pull wire attached to the distal end of the catheter would have been considered obvious in view of the proven conventionality of this particular catheter body design, and moreover, because the use of a slotted body provides higher degree of flexibility resulting in a more maneuverable catheter.

In relation to claims 10-14 and 16-21, and as stated above, Middleman shows in figures 1B and 1C, a stiffener that is located within the body of the catheter. The Winnie patent shows in figures 2 and 3, a stiffener that comprises of a sleeve located outside the body of the catheter. The Sylvanowicz patent shows in figures 1-4, another stiffener that comprises of a sleeve located outside the body of the catheter.

Based on the observations above, for a person of ordinary skill in the art, modifying the Rosenblum patent with a stiffeners that are located within the body of the catheter or comprise of a sleeve located over the outer surface of the catheter, would have been considered obvious in view of the proven conventionality of these enhancements, and moreover, because the addition of a stiffener would have enhanced the maneuverability of the catheter system by providing a more efficient curve adjustment mechanism.

Claims 22-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenblum** (US 4976688) in view of **DeLaRama** et al. (US 5381782; hereafter DeLaRama), and in further view of **Giba et al.** (US 5876373; hereafter Giba), **Hanson** et al. (US 5709874; hereafter Hanson), **Brown** et al. (US 6053900; hereafter Brown), **Greenwood** et al. (US 5004455; hereafter Greenwood), **Sepetka** et al. (US 5882334; hereafter Sepetka), **Naimark** et al. (US 7455657; hereafter Naimark), or **West** et al. (US 5318525; hereafter West).

The Rosenblum patent does not specifically disclose the step of ejecting a therapeutically sufficient amount of agent into the body, a structure that is tissue (vein or artery), an organ, a cavity, or the heart (claims 22-28). However, the Giba patent

demonstrates the conventionality using a steerable catheter for the infusion of agents into the body to perform therapeutic treatments. The infusion can be performed to treat tissue, an organ, a cavity, or the heart. Accordingly, the use of a catheter to infuse agents into any of the above locations within a body would have been considered obvious alternatives in the design of the catheter in view of the conventionality of the discussed intended uses.

The Rosenblum patent does not specifically disclose the step of delivering agents into a bladder or urethra (claims 29 and 30). However, the Hanson patent discloses the use of a catheter to deliver agents into the bladder or urethra. Accordingly, the use of a catheter to infuse agents into any of the above locations within a body would have been considered obvious alternatives in the design of the catheter in view of the conventionality of the discussed intended uses. In relation to claim 30, the cited patents infuse fluid therapeutic agents.

The Rosenblum patent does not specifically disclose the step of delivering agents comprising of radiation (claim 31). However, the Brown patent discloses the use of a catheter to deliver an agent comprising of radiation. Accordingly, the use of a catheter to deliver radiation within a body would have been considered an obvious alternative in the design of the catheter in view of the proven conventionality of this particular enhancement.

The Rosenblum patent does not specifically disclose the step of delivering agents comprising of antibiotics (claim 32). However, the Greenwood patent discloses the use of a catheter to deliver an agent comprising of an antibiotic. Accordingly, the

use of a catheter to deliver an antibiotic within a body would have been considered an obvious alternative in the design of the catheter in view of the proven conventionality of this particular enhancement.

The Rosenblum patent does not specifically disclose the step of delivering agents comprising of ethanol (claim 33). However, the Sepetka patent discloses the use of a catheter to deliver an agent comprising of ethanol. Accordingly, the use of a catheter to deliver ethanol within a body would have been considered an obvious alternative in the design of the catheter in view of the proven conventionality of this particular enhancement.

The Rosenblum patent does not specifically disclose the step of delivering agents comprising proteins or polypeptides (claim 34). However, the Naimark patent discloses the use of a catheter to deliver agents comprising of proteins or polypeptides. Accordingly, the use of a catheter to deliver proteins or polypeptides within a body would have been considered an obvious alternative in the design of the catheter in view of the proven conventionality of these particular enhancements.

The Rosenblum patent does not specifically disclose the step of delivering agents comprising of thermal energy (claim 35). However, the West patent discloses the use of a catheter to deliver thermal energy. Accordingly, the use of a catheter to deliver thermal energy within a body would have been considered an obvious alternative in the design of the catheter in view of the proven conventionality of this particular enhancement.

Claims 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenblum** (US 4976688) in view of [**Muto** (US 4512765) or **Bowe** (US 6592581)], and in further view of **DeLaRama** et al. (US 5381782; hereafter DeLaRama), and in further view of **Giba et al.** (US 5876373; hereafter Giba), **Hanson** et al. (US 5709874; hereafter Hanson), **Brown** et al. (US 6053900; hereafter Brown), **Greenwood** et al. (US 5004455; hereafter Greenwood), **Sepetka** et al. (US 5882334; hereafter Sepetka), **Naimark** et al. (US 7455657; hereafter Naimark), or **West** et al. (US 5318525; hereafter West).

The Rosenblum patent does not specifically disclose the step of advancing a mechanical agent. However, the use of catheters to advance mechanical agents would have been considered conventional in the art as evidenced by the teachings of Muto or Bowe. The Muto patent demonstrates the conventionality of advancing, manipulating, and actuating a suction tube in a body. The Bowe patent demonstrates the conventionality of advancing, manipulating, and actuating a sensor in a body. Based on the above observations, for a person of ordinary skill in the art, modifying the Rosenblum steerable catheter with the capability of advancing, manipulating, and actuating a mechanical agent, as taught by Muto or Bowe, would have been considered obvious in view of the proven conventionality of these enhancements, and moreover, because such applications would have enhanced the capabilities of the catheter to perform more procedures in the body.

The Rosenblum patent does not specifically disclose the step of ejecting a therapeutically sufficient amount of agent into the body, a structure that is tissue (vein or

artery), an organ, a cavity, or the heart (claims 37-42 and 44). However, the Giba patent demonstrates the conventionality using a steerable catheter for the infusion of agents into the body to perform therapeutic treatments. The infusion can be performed to treat tissue, an organ, a cavity, or the heart. Accordingly, the use of a catheter to infuse agents into any of the above locations within a body would have been considered obvious alternatives in the design of the catheter in view of the conventionality of the discussed intended uses.

The Rosenblum patent does not specifically disclose the step of delivering agents into a bladder or urethra (claims 43). However, the Hanson patent discloses the use of a catheter to deliver agents into the bladder or urethra. Accordingly, the use of a catheter to infuse agents into any of the above locations within a body would have been considered obvious alternatives in the design of the catheter in view of the conventionality of the discussed intended uses. In relation to claim 30, the cited patents infuse fluid therapeutic agents.

The Rosenblum patent does not specifically disclose the step of delivering agents comprising of thermal energy (claim 44). However, the West patent discloses the use of a catheter to deliver thermal energy. Accordingly, the use of a catheter to deliver thermal energy within a body would have been considered an obvious alternative in the design of the catheter in view of the proven conventionality of this particular enhancement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM